

### **REMARKS**

Further and favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

#### **Claim Amendments**

Claims 10, 37, 57 and 62-65, which are the only independent claims, have been amended to delete the polyoxyethylene sorbitan fatty acid ester and the polyoxyethylene alkyl ether to further clarify the components of the surfactant mixture.

In light of the amendment to claim 10, claim 19 has been amended to clarify that the mixture of surfactants “further comprises” a polyoxyethylene sorbitan fatty acid ester and a polyoxyethylene alkyl ether.

Claim 37 has been amended to delete the recitation of the preferred ratio, i.e., “preferably between 1:5 and 1:3”, in light of which claim 66 has been added to recite the preferred ratio.

#### **Office Action of June 22, 2010**

Applicants acknowledge that a non-final Office Action was issued on June 22, 2010 in the present application. However, the Action was never received by Applicants’ representatives because it was mailed to an outdated address of the representatives.

On July 21, 2010, Ms. Brenda Gray of Patent Technology Center 1600 contacted Applicants’ representatives by telephone and indicated that the Office Action of June 22, 2010 had been returned to the PTO undelivered. Applicants’ representatives directed Ms. Gray to the previously filed Change of Correspondence Address forms, which Ms. Gray indicated had not been processed because they were not signed by an attorney of record in the case. Applicants’ representatives indicated that they did not believe that such forms had to be signed by an attorney of record. After conferring with her SPE, Ms. Gray confirmed that the Change of Correspondence Address forms were not required to be signed by an attorney of record and therefore, she would process the change of correspondence address, issue a new Office Action and restart the due date.

Based on Ms. Gray’s comments, Applicants have disregarded the Office Action of June 22, 2010, and hereby respond to the correctly addressed Office Action mailed July 27, 2010.

**Rejection Under 35 U.S.C. § 112, Second Paragraph**

The rejection of claims 29, 31, 33-40, 52-56, 59 and 60 under 35 U.S.C. § 112, second paragraph, as being indefinite, has been rendered moot by the amendment to claim 37, which deletes the recitation of the preferred ratio.

Accordingly, this rejection should be withdrawn.

**Rejections Under 35 U.S.C. § 103(a)**

The patentability of the present invention over the disclosures of the references relied upon by the Examiner in rejecting the claims will be apparent upon consideration of the following remarks.

The rejection of claims 10-20, 57 and 62-65 under 35 U.S.C. § 103(a) as being unpatentable over Miano et al. (US 3,931,824, hereinafter Miano) is respectfully traversed.

Specifically, Miano fails to teach or suggest a surfactant mixture containing an  $\alpha$ -hydroxy- $\omega$ -hydroxypoly(oxyethylene)poly(oxypropylene)poly(oxyethylene) block copolymer and a polyoxyethylene castor oil derivative (see col. 6, lines 4-14 of Miano) as required by the present invention. Therefore, the presently claimed monolayer film is not obvious over Miano.

Moreover, the technical field of Miano is not sufficiently related to the field to which the present invention pertains, i.e., a skilled person in the art desiring to make a mucoadhesive composition for delivering pharmaceutically active agents to a mucous membrane (present invention) would not have considered a prior art document which is concerned with a smoking material or combustible material (Miano).

Accordingly, a person having ordinary skill in the art would not have assumed that a selection from the mixture of surfactants of Miano (for a smoking material) would fulfill the same technical functions and produce the same technical effects of the present invention (for a mucoadhesive composition for delivering pharmaceutically active agents to a mucous membrane).

As stated in col. 6, lines 4-5, of Miano, the addition of a wetting agent serves to improve film formation. In contrast, in the present invention, the addition of the specific binary surfactant mixture serves to achieve the desired wettability of the monolayer film

(see paragraphs [0011, 0013] of the published application). Moreover, the films disclosed in Miano contain a particular filler material (see col. 3, lines 47-62 and claim 1), which is expected to impede film formation, thus requiring the addition of the wetting agent so that film formation is improved despite the presence of the particular filler material. In fact, according to Miano, the wetting agent is added for the sole reason of improving film formation (see col. 6, lines 4-14). Therefore, the wetting agent is not taught to have any useful function once film formation is complete. Since the films taught by Miano are destined to be burned/combusted, it is quite clear that the wetting agent has no particular function in the product itself.

The Examiner appears to believe that properties such as “instant wettability... followed by rapid dissolution” (see present claim 37) are due to the polymers used for producing the film (see p. 6, last line, to p. 7, line 1, of the Office Action: “...should have the same properties because the polymers control the wettability and dissolution of the film”). However, the Examiner’s statement does not appear to be substantiated by facts. Moreover, contrary to the Examiner’s position, the present specification clearly teaches that instant wettability is achieved by the selection of a binary surfactant mixture as defined in the present claims (see paragraph [0013] of the published application).

Accordingly, it would not have been obvious to a person having ordinary skill in the art to combine an  $\alpha$ -hydroxy- $\omega$ -hydroxypoly(oxyethylene)poly(oxypropylene)poly(oxyethylene) block copolymer and a polyoxyethylene castor oil derivative to obtain mucoadhesive compositions having the properties specified in present claim 10.

The rejections on pages 7-12 of the Office Action are also overcome for the reasons indicated above, since these rejections are based on the teachings of Miano in combination with other references.

Thus, all rejections should be withdrawn since the current amendments render the reasons for allowability as set forth on pages 7-8 of the Office Action mailed December 1, 2009, applicable again as applied to the currently employed binary mixture of surfactants.

**Conclusion**

Therefore, in view of the foregoing amendments and remarks, it is submitted that each of the grounds of rejection set forth by the Examiner has been overcome, and that the application is in condition for allowance. Such allowance is solicited.

If, after reviewing this Amendment, the Examiner feels there are any issues remaining which must be resolved before the application can be passed to issue, the Examiner is respectfully requested to contact the undersigned by telephone in order to resolve such issues.

Respectfully submitted,

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